K062340

ATTACHMENT 4

510(k) Summary

NOV 30 2006

CardioOptics Augmentative Cardiac Optical Imaging System

Applicant Name:	Cardio-Optics, Inc. 2425 55th St. Suite 100 Boulder, Colorado 80301 USA Phone: (720) 406-1560 Fax: (720) 406-1562
Contact Person:	Larry O. Blankenship Chief Operating Officer
Date Prepared:	November 3, 2006
Device Trade Name:	CardioOptics Augmentative Cardiac Optical Imaging System
Common Name:	Angioscope
Classification Name:	Angioscope (21 CFR 876.1500 Product Code: LYK)
Predicate Devices:	CSA™ System, K050808 FSEA Fiberscope, K011763 Olympus Angioscopes, K911278 & K860858 ACUSON AcuNav™ 8F-110 Ultrasound Catheter, K042593 EPMed Systems ViewFlex Catheter, K031066
Device Description:	The CardioOptics Augmentative Cardiac Optical Imaging System is composed of a single-use catheter, accessories, and an Image Acquisition System. The system incorporates infrared light (IR) technology to provide visualization through flowing blood. This submission modifies the indications for use originally cleared in 510(k) No. K050808 to include visualization of the cardiac chambers and great vessels.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2006

CardioOptics, Inc.
c/o Larry Blankenship, Chief Operating Officer
2425 55th Street
Suite 100
Boulder, CO 80301

Re: K062340
Trade/Device Name: CardioOptics Augmentative Cardiac Optical Imaging System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: LYK
Dated: November 3, 2006
Received: November 6, 2006

Dear Mr. Blankenship:

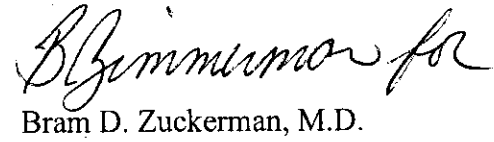
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 3

INDICATIONS FOR USE STATEMENT

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510(k) Number (if known): K062340

Device Name: CardioOptics Augmentative Cardiac Optical Imaging System

Indications for Use:

The CardioOptics Augmentative Cardiac Optical Imaging System is intended to image anatomical structures within the chambers of the heart and great vessels. The system is to be used in conjunction with fluoroscopic imaging.

The system is also indicated for accessing the coronary sinus for pacemaker lead implantation. The system includes visualization means to image anatomical structures to augment navigation into the coronary sinus.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062340